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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09/484,331	01/18/2000	John J. Harrington	5817-71	9576

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EXAMINER

SEUKER, RAMER

ART UNIT	PAPER NUMBER
	32

DATE MAILED:

Please find below and or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/484,331	HARRINGTON ET AL.	
	Examiner	Art Unit	
	Ram R. Shukla	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *62-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *62-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The response and amendment filed 6-26-02 have been entered.

2. Claim 69 has been entered.

3. Claims 62-69 are pending in the instant application.

Priority

4. Assigning of priority to the instantly claimed invention to the filing date of 09/276820, that is 3-26-99, is maintained. Applicants have argued that the 08/941,223 disclosed invention on certain sections, however, none of the indicated pages recite a drug discovery method as instantly claimed.

Specification

5. The abstract of the disclosure is objected for reasons of record set forth in the office action of 10-25-01.

Applicants' response that the abstract will be amended when the substantive issues have been resolved is acknowledged.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 62-68 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record set forth in the previous office action of 10-25-01.

Applicant's arguments filed 6-26-02 have been fully considered but they are not persuasive. Applicants have argued that the structure of the compounds is not relevant and in support they have attached a declaration by Y. Bennani, director of Medicinal Chemistry at Athersys Inc, assignee of the instant invention and a slide presentation by Brian Stanton, BPS, USPTO. The declaration by Dr. Bennani has been considered, however the declaration is not persuasive to obviate the rejection. In the declaration, Dr. Bennani has stated that in view of his experience, structure of compounds is not important, however, applicants arguments are not evidence. In other words, applicants have provided any evidence of record that indicates that structure of compounds is irrelevant in drug discovery assay. Next, regarding Brian Stanton's handout, it is noted that there is no special reference to the claimed invention in the hand out therefore, it is not clear as to how applicants interpreted that the written description in their application was met. Next, applicants used an example of US patent 6,159,705 that has a genus claim, however, the patent is not relevant because the cited patent describes assay for compounds relating to a certain receptor in a certain cell type and based on the structure of the peptides the written description requirement is met. In the instant application, on the other hand, the method is not to a certain gene and there is not representative compound described. Therefore, the two situations (cited patent and the instant invention) are not equivalent.

It is emphasized that the only description/reference to a drug in the specification is in lines 28-30 on page 11 continued in lines 1-2 on page 12. Applicants have not provided any description of compounds that will be used in the assay.

Therefore, the written description is maintained for reasons of record.

8. Claim 62-68 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it

is most nearly connected, to make and/or use the invention for reasons of record set forth in the previous office action of 10-25-01.

Applicant's arguments filed 6-26-02 have been fully considered but they are not persuasive. Applicants' arguments that page 46, lines 8-11 provide enablement for activation by any vector is not persuasive because the indicated section of the specification does not teach how the claimed method will be carried using any vector and neither the arguments nor the cited section of the specification address the issue raised in the previous office action.

Regarding the issue of: is the claimed method a method of drug screening, applicants indicate to point 4 in the declaration. However, point 4 does not address the issues raised in the office action- the steps of the claimed invention do not represent in any way represent a method of treatment, diagnosis, alleviation or prevention or cure of a disease and by practicing the claimed method an artisan of skill would not be able to determine whether a compound that was isolated by the claimed screening method would have any of the properties of a drug. It is noted that the claimed method is a drug discovery method, not just screening for a compound. Applicants argue that a compound that affects gene expression will be a drug candidate, however, applicants ignore the fact that the method is for screening a drug not a candidate drug. Applicants discuss philosophy of drug industry, however, the discussion is not relevant to the issue of enablement. Applicant's argument that structure of the compound is not relevant is not persuasive and does not address the issue raised in the previous office action. Regarding, the cited patent, applicants arguments are not persuasive because as noted in the written description rejection, the cited patent is for screening in yeast cells and for a certain receptor. Additionally, applicants argue that with just the "drug discovery" artisan of

ordinary skill would have recognized are not persuasive because the specification has to describe what is the invention.

Courts have stated:

It is noted that patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. See Brenner v. Manson, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.

Courts also stated, "It is true, as Genentech argues, that a specification need not disclose what is well known in the art. See, e.g., Hybritech Inc. v. Monoclonal Antibodies, Inc. , 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement." (See Brenner v. Manson, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966))

In the instant case, the specification fails provide any guidance as to how a method of drug discovery will be carried out. Regarding the issue of "desired gene", applicants argue that this was resolved however Examiner does not agree that the issue raised instantly was resolved. It is reiterated that the instant issue is: that even when a cell in which a desired gene is activated, there is no way of knowing if the desired phenotype observed in a selected cell is due to the activated expression of only the desired gene or due to a activation of multiple genes. In fact, the specification on page 32, lines 28-30, states that a single cell or different cells in a set of transfectants

(library) can over express more than one protein following transfection with the same or different constructs.

Regarding the declaration by Dr. Bennani, it is noted that the declaration notes eight steps of a drug discovery process. It is emphasized that according to the declaration, the process starts with linking a gene to a disease state and then establishing an assay method for activation. It is emphasized that in the instant case, not such linking is established. In fact, examiner has argued this point all along that for a drug discovery one has to know what gene is to be activated and as established in record in several applications pending or allowed (by the applicants), the novelty of the invention is activating a gene at random and not a certain gene. Therefore, the declaration fails to address the issue raised in the previous office action. It is noted that the declaration does not have any specific information or any evidence to address the issues raised in the previous office action.

In summary, the specification, except for a reference to use of the claimed cell for potential therapeutic compound screening, there is not disclosure in the specification as to how the method of screening would be performed and therefore, an artisan would not have any guidance from the specification or in the prior art for practicing the claimed invention and would require extensive experimentation for determining as to how use any vector in activating endogenous gene expression, what compounds with what structure or characteristics to use in the claimed method, therapeutic efficacy of compounds, etc., as discussed above. It is noted that such experiments would not have been routine at the time of the invention and therefore, an artisan would have required undue experimentation to practice the claimed invention. Therefore, the enablement rejection is maintained for reasons of record set forth in the previous office action of 10-25-01.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 62-68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejection of claims 62 and 63 for the lack of antecedent basis is maintained for reasons of record. Applicants have not presented any argument as to how the proper antecedent basis was present.

Claim 62 and 63 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps is maintained for reasons of record. Applicants arguments are not persuasive because applicants provide no evidence as how the missing steps are not required for the method, rather they have argued that any numbers of critical steps could be added. If so, these critical steps should be added. Regarding the issue of comparison step with the parental cell, it is noted that the step of comparison with the parent cell is critical for determining whether a desired gene has been activated.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

12. Claims 62 and 66 are rejected under 35 U.S.C. 102(e) as being anticipated by Truecheart et al (US 6,159,705, 12-12-00, effective filing date

9-24-1996) for reasons of record set forth in the previous office action of 10-25-01.

Applicant's arguments filed 6-26-02 have been fully considered but they are not persuasive. Applicants argue that the test compound interacts with the receptor and not the indicator. However, there is not indicator in the instantly claimed invention, therefore, it is not clear how it is relevant. Additionally, the compound interacts with the receptor for which the compound is to screened, therefore, it meets the limitation that the compound interacts with the gene product.

13. No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

When amending claims, applicants are advised to submit a clean version of each amended claim (without underlining and bracketing) according to § 1.121(c). For instructions, Applicants are referred to http://www.uspto.gov/web/offices/dcom/olia/aipa/index.htm.

Applicants are also requested to submit a copy of all the pending/under consideration claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for this Group is (703) 308-4242. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the Tiffiany N. Tabb whose telephone number is (703) 605-1238.

Ram R. Shukla, Ph.D.

RAM R. SHUKLA, PH.D
PATENT EXAMINER